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10/658,438	09/09/2003	Jeffrey W. Leon	85694LMB	4708

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EXAMINER	
JUNG, UNSU	

ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/658,438	LEON ET AL.	
	Examiner	Art Unit	
	Unsu Jung	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) *53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/9/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-53, drawn to a microarray, classified in class 435, subclass 287.8, for example.

   II. Claim 54, drawn to method of using a microarray, classified in class 435, subclass 4, for example.

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process. For example, the microarray of Group I can be used to detect biological targets using non-optical detection methods such as electrochemical methods.

4. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art because of their recognized divergent subject matter, and

searches for one group are not required by the others, restriction for examination purposes as indicated is proper.

5. During a telephone conversation with Ms. Blank on May 23, 2005 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-53. Affirmation of this election must be made by applicant in replying to this Office action. Claim 54 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

7. The use of the trademark TESLIN® (p5, line 29, TYVEK® (p5, line30), OPPALYTE® (p5, line 30), XAMA-7® (p15, line 1), CYMEL® (p15, line 5), CYMEL 300® (p15, line 5), CYMEL 303® (p15, line 5), CYMEL 1170® (p15, line 6), CYMEL 1171® (p15, line 6), EPON® (p15, line 7), FC-439® (p16, line 9), FC-341® (p16, line 9), FC-10® (p16, line 9), FC-171R® (p16, line 9), ZONYL® (p16, line 10), ZONYL-FSN® (p16, line 10), ZONYL-FTX® (p16, line 11), ZONYL-TBS® (p16, line 11), ZONYL-BA® (p16, line

11), MODIPER F600® (p16, line 12), DC 1248® (p16, line 13), DC200® (p16, line 13), DC510® (p16, line 13), DC 190® (p16, line 13), BYK 320® (p16, line 14), BYK 322® (p16, line 14), SF 1079® (p16, line 14), SF 1023® (p16, line 14), SF 1054® (p16, line 14), SF 1080® (p16, line 15), SILWET® (p16, line 15), SPAN® (p16, line 17), PLUONIC® (p16, line 18), TRITON X® (p16, line 19), ALKANOL® (p16, line 20), and DOWFAX® (p16, line 21) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 9, 13, 28 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 9 recites the limitation "said specific functionalities" in line 1. There is insufficient antecedent basis for this limitation in the claim.

11. Claim 13 recites the limitation "said specific functionalities" in line 1. There is insufficient antecedent basis for this limitation in the claim.

12. Regarding claims 28 and 33, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1-4, 8-11, 43, 44, 45, and 47-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Wohlstadter et al. (U.S. Patent No. 6,066,448, May 23, 2000).

Wohlstadter et al. anticipates instant claims by teaching a microarray (column 11, lines 56-58) comprising a support having attached to a surface thereof at least one porous layer, wherein the porous layer comprises a hydrophilic binder (column 17, lines 17-19) and polymer particles (column 14, line 45-column 15, line 24 and column 15, lines 59-62).

With respect to claim 2, Wohlstadter et al. teaches a microarray of claim 1, wherein the polymer particles comprise one or more polymers (column 14, line 45-column 15, line 24).

With respect to claims 3 and 4, Wohlstadter et al. teaches a microarray of claim 1, wherein the polymer particles comprise water-insoluble synthetic polymers such as polyacrylamide (column 14, lines 46-48).

With respect to claims 8-11, Wohlstadter et al. teaches a microarray of claim 1, wherein the polymer particles comprise chemically active groups comprising at least one member selected from the group consisting of thiols (column 13, line 13) and carboxylic acids (column 13, line 15).

With respect to claims 43 and 44, Wohlstadter et al. teaches a microarray of claim 1, further comprising a bioaffinity tag bound to hydrophilic binder of the porous layer (column 11, lines 44-47) in a spatially addressable manner (column 12, lines 22-26).

With respect to claim 45, Wohlstadter et al. teaches a microarray of claim 43, wherein the bioaffinity tag is bound to the polymer particle of the porous layer (column 14, line 67-column 15, line 24).

With respect to claim 47, Wohlstadter et al. teaches a microarray of claim 43, wherein the bioaffinity tag comprises at least one member selected from the group consisting of DNA, antibodies, antigens, proteins, enzymes, nucleic ligands, and polysaccharides (column 20, lines 40-60).

With respect to claim 48, Wohlstadter et al. teaches a microarray of claim 1, wherein the porous layer comprises from 5 to 2000 microns thick (column 14, lines 7-10).

With respect to claim 49, Wohlstadter et al. teaches a microarray of claim 1, wherein the layer comprises more than a single layer to produce a three-dimensional array (column 40, lines 15-19).

With respect to claim 50, Wohlstadter et al. teaches a microarray of claim 1, wherein the porous layer may also include crosslinking agents (column 15, lines 7-10).

With respect to claims 51 and 52, Wohlstadter et al. teaches a microarray of claim 1, wherein the support comprises glass (column 12, lines 5-9).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 5, 13, 16-24, 36-42, 46, and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wohlstadter et al. (U.S. Patent No. 6,066,448, May 23, 2000) in view of Pierce et al. (U.S. Patent No. 4,258,001, Mar. 24, 1981).

Wohlstadter et al. teaches a microarray as discussed above. However, Wohlstadter et al. fails to teach a microarray, wherein the polymer particles comprise monodisperse polymer particles, stabilizer polymers comprise pendant vinylsulfonyl or latent vinylsulfonyl groups, and hydrophilic binder comprise gelatin.

Pierce et al. teaches a particulate structure on a support surface containing interactive compositions useful for the analysis of various substances in liquids (Abstract, lines 18-20). The particulate structure can readily take up, uniformly distribute within itself, meter, rapidly transport applied liquid samples containing any of a

wide variety of analytes (column 3, lines 46-50), and is particularly suited for immunoassay (column 6, lines 41-43). Although shape and size of the organo-polymeric particles can vary widely, in a preferred embodiment, these particles are of substantially uniform size (column 9, lines 35-37). The size of the organo-polymeric particles regulate to an extent, the size of the void spaces contained in the particulate structure of the element (column 9, lines 42-44).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the microarray of Wohlstadter et al. polymer particles having a substantially uniform size distribution defined as being monodisperse by Pierce et al. (column 30, line 42) in order to readily take up, uniformly distribute within itself, meter, and rapidly transport applied liquid samples containing any of a wide variety of analytes for immunoassays.

With respect to claims 13 and 16, Pierce teaches a method of using a polymer comprising vinylsulfonyl group (column 12, lines 36-42) to stabilize polymer particle dispersion (column 17, lines 43-55).

With respect to claims 17-20 and 24, Pierce et al. teaches a stabilizer polymers comprising ionic monomers such as acrylic and methacrylic acids (column 11, lines 59-60), which have a weight percentage ranging from 0-30%, crosslinked with vinylsulfonyl group having a weight percent ranging from 1-20% (column 12, line 23 and lines 36-42). Therefore, it would be obvious to one skill in the art to realize that the combination of ionic monomers and crosslinking group having the weight range as discussed above

would encompass the molar percentages ranging from 25 to 75 and 75 to 25 for x and y in Formula I, respectively.

With respect to claims 21-23, Pierce et al. teaches a stabilizer polymer comprising nonionic monomers such as acrylamide (column 12, line 3) and metacrylamide (column 12, line 3), which have weight percent ranging from 0-20% (column 12, line 52).

With respect to claims 36 and 37, Pierce et al. teaches a method of coating an adherent layer of hydrophilic colloid (hydrophilic binder) such as gelatin or poly(vinyl alcohol) to bond together polymer particles (column 2, lines 3-5 and column 2, lines 34-40).

With respect to claim 38, Pierce et al. teaches a hydrophilic binder comprising poylmerizable monomers as described in groups (g1) and (g2) containing alkali metals (column 12, lines 26-42 and column 15, line 14).

With respect to claims 39-41, Pierce et al. teaches a hydrophilic binder comprising chemically active groups rich in specific functionalities such as vinylsulfonyl group (column 12, lines 36-42).

With respect to claim 42, Pierce et al. teaches a hydrophilic binder comprising vinylbenzylamine (column 12, lines 19-20).

With respect to claim 46, Pierce et al. teaches a stabilizer polymer, which is a part of the particulate structure and comprise polymers containing an active linking or bonding site, can advantageously be chemical bonded to one or more components of a particular interactive composition (bioaffinity tag, column 21, lines 10-25).

With respect to claim 53, Pierce et al. teaches a support having a subbing layer between the porous layer and the support (Fig. 5, and column 22, lines 35-37).

19. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wohlstadter et al. (U.S. Patent No. 6,066,448, May 23, 2000) in view of Pierce et al. (U.S. Patent No. 4,258,001, Mar. 24, 1981) as applied to claim 5 above, and further in view of Waki et al. (US 2001/0022769, Filed Mar. 19, 2001).

Wohlstadter et al. in view of Pierce et al. teaches a microarray as discussed above. Pierce et al. teaches that the particulate structure on a support surface can readily take up, uniformly distribute within itself, meter, rapidly transport applied liquid samples containing any of a wide variety of analytes (column 3, lines 46-50), and is particularly suited for immunoassay (column 6, lines 41-43). Although shape and size of the organo-polymeric particles can vary widely, in a preferred embodiment, these particles are of substantially uniform size (column 9, lines 35-37). The size of the organo-polymeric particles regulate to an extent, the size of the void spaces contained in the particulate structure of the element (column 9, lines 42-44). However, Wohlstadter et al. in view of Pierce et al. fails to teach a microarray, wherein the monodisperse polymer particles have a particle size distribution with coefficient of the particle size distribution less than 10%.

Waki et al. teaches a method of making monodisperse polymer particles with a narrow particle size distribution. The monodisperse particles have a coefficient of variation of less than 10% (column 3, lines 9-11).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the microarray of Wohlstadter et al. in view of Pierce et al. with a monodisperse polymer particle having coefficient of variation of less than 10% as taught by Waki et al. in order to attain uniform size distribution for particulate structure on a support surface to readily take up, uniformly distribute within itself, meter, rapidly transport applied liquid samples containing any of a wide variety of analytes for immunoassays.

20. Claims 12, 27-30, 34, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wohlstadter et al. (U.S. Patent No. 6,066,448, May 23, 2000) in view of Snyder et al. (U.S. Patent No. 5,094,962, Mar. 10, 1992).

Wohlstadter et al. teaches a microarray as discussed above. However, Wohlstadter et al. fails to teach a microarray, wherein the polymer particles comprise chemically active groups, which comprise vinylsulfonyl units and stabilizer polymers comprise at least one member selected from the group consisting of acrylic acid and (meth)acrylic acid. Wohlstadter et al. further fails to teach a microarray, wherein polymer particles comprise at least one ethylenically unsaturated polymerizable monomer.

Snyder et al. teaches a method of preparing microporous substrate having a first and second outer surfaces and having affixed to at least one of the surfaces a composition comprising a specific binding reagent, which comprises water-insoluble particles to which are attached receptor molecules to the target ligand, the reagent

admixed with one or more hydrophilic, neutral or positively-charged polymeric binders (column 2, lines 50-57). The significantly improved keeping stability is achieved with a water-insoluble microporous article for use in a ligand-receptor assay to detect a target ligand (column 2, lines 47-49). The reagents are prepared using polymeric particles, which have suitable reactive groups for covalently attaching the receptor molecules thereto (column 6, lines 35-37). Covalent attachment of receptor is usually accomplished using surface reactive groups, which are capable of reacting directly or indirectly with free amine or vinylsulfonyl groups of the ligand (column 6, lines 45-49). Such surface reactive groups include vinylsulfonyl and other groups known in the art (column 6, lines 46-49).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the microarray of Wohlstadter et al. with polymeric particles having vinylsulfonyl as a reactive group as taught by Snyder et al. in order to covalently attach the receptor molecules thereto for use in a ligand receptor assay to detect a target ligand.

With respect to claim 27, Snyder et al. teaches polymer particles comprise at least one ethylenically unsaturated polymerizable monomer (column 6, lines 57-59).

With respect to claim 28, Snyder et al. teaches at least one ethylenically unsaturated polymerizable monomer comprises at least one member selected from the group consisting of methacrylic esters, acrylate esters, and styrenes (column 6, line 62-column 8, line 28).

With respect to claim 29, Snyder et al. teaches at least one ethylenically unsaturated polymerizable monomer comprises chemical functionalities (column 6, lines 41-49).

With respect to claim 30, Snyder et al. teaches the chemical functionalities comprise vinyl groups (column 6, lines 48-49).

With respect to claims 34 and 35, Snyder et al. teaches polymer particles having a mean diameter of from 0.01 to 5 microns.

21. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wohlstadter et al. (U.S. Patent No. 6,066,448, May 23, 2000) in view of Pierce et al. (U.S. Patent No. 4,258,001, Mar. 24, 1981) as applied to claim 13 above, and further in view of Snyder et al. (U.S. Patent No. 5,094,962, Mar. 10, 1992).

Wohlstadter et al. in view of Pierce et al. teaches a microarray comprising a stabilizer polymer as discussed above. Pierce et al. teaches a stabilizer polymer comprising a monomer blend containing from monomers selected from groups (a)-(k) (column 14, lines 58-61) such as acrylamide (column 12, line 3) having a crosslinking vinylsulfonyl group (column 12, lines 36-42). However, Wohlstadter et al. in view of Pierce et al. fails to teach a microarray, wherein stabilizer polymers comprise at least one member selected from group consisting of poly(propyleneimine), polymers and copolymers of methacrylic acid, acrylic acid, mercaptomethyl styrene, N-aminopropyl(meth)acrylamide and secondary amine derivatives thereof, N-aminoethyl(meth)acrylate and secondary amine forms thereof, diallyamine,

vinylbenzylamine, vinylamine, (meth)acrylic acid, vinylbenzyl mercaptan, and hydroxyethyl(meth)acrylate.

Snyder et al. teaches a method of preparing microporous substrate having a first and second outer surfaces and having affixed to at least one of the surfaces a composition comprising a specific binding reagent, which comprises water-insoluble particles to which are attached receptor molecules to the target ligand, the reagent admixed with one or more hydrophilic, neutral or positively-charged polymeric binders (column 2, lines 50-57). The significantly improved keeping stability is achieved with a water-insoluble microporous article for use in a ligand-receptor assay to detect a target ligand (column 2, lines 47-49). The reagents are prepared using polymeric particles, which have suitable reactive groups for covalently attaching the receptor molecules thereto (column 6, lines 35-37). It is critical for keeping stability of the reagent that it be admixed with a hydrophilic, neutral or positively charged binder material, thereby forming a specific binding composition (column 4, lines 52-56). The binder material improves the keeping stability of the reagent considerably over the same reagent used without the binder material (column 4, lines 60-62).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the microarray of Wohlstadter et al. in view of Pierce et al. with hydrophilic, neutral or positively charged binder material admixed with reagent comprising polymer particles as taught by Snyder et al. in order to improve stability of reagent.

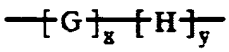
With respect to claim 14, Snyder et al. teaches a stabilizer polymers comprise at least one member selected from the group consisting of acrylic acid and (meth)acrylic acid (column 5, lines 14-38).

With respect to claim 15, Snyder et al. teaches a stabilizer polymers comprise at least one member selected from the group consisting of polyacrylic acid and polymethacrylic acid (column 5, lines 14-38).

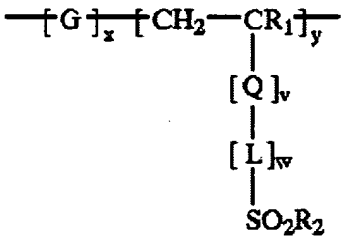
22. Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wohlstadter et al. (U.S. Patent No. 6,066,448, May 23, 2000) in view of Pierce et al. (U.S. Patent No. 4,258,001, Mar. 24, 1981) as applied to claims 13, 16, and 17 above, and further in view of Ogawa et al. (U.S. Patent No. 4,548,869, Oct. 22, 1985).

Wohlstadter et al. in view of Pierce et al. teaches a microarray comprising a stabilizer polymer as discussed above. Pierce et al. teaches a stabilizer polymer comprising a monomer blend containing from monomers selected from groups (a)-(k) (column 14, lines 58-61) such as acrylamide (column 12, line 3) having a crosslinking vinylsulfonyl group (column 12, lines 36-42). However, Wohlstadter et al. in view of Pierce et al. fails to teach a microarray, wherein the vinylsulfone or vinylsulfone precursor "H" of Formula I represents groups represented by Formula II:

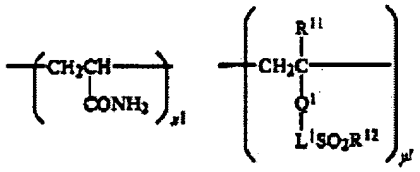
Formula I



Formula II



Ogawa et al. teaches an adhesive layer to improve adhesion between a support and a polyacrylamide gel medium (column 2, lines 34-37) and the adhesive layer comprising a polymer having at least one specifically selected repeated unit having the following formula:



in which R^{11} is a hydrogen atom or an alkyl group containing 1-6 carbon atoms;

Q^1 is –COO–, CON(R^{11})– or an arylene group containing 6-10 carbon atoms;

L^1 is a divalent group containing at least one linkage selected from the group consisting of –COO– and –CON(R^{11})– and containing 3-15 carbon atoms, or divalent atom containing at least one linkage selected from the group consisting of –O–, –N(R^{11}) –, –CO–, –SO–, –SO_2–, –SO_3–, –SO_2N(R^{11}) –, –N(R^{11})CON(R^{11}) and –N(R^{11})COO–, and containing 1-12 carbon atoms, in which R^{11} has the same meaning as defined above;

R^{12} is $-CH=CH_2$ or $-CH_2CH_2X^1$, in which X^1 is a substituent replaceable with a nucleophilic group or releasable in the form of HX^1 by a base and x^1 and y^1 both representing molar percentage range from 0 to 99 and from 1 to 100, respectively, and x^1+y^1 is not less than 90 (column 2, line 47-column 3, line 12). Ogawa et al. further teaches a process for synthesis of ethylenic unsaturated monomers containing a vinylsulfonyl group or function group convertible into vinylsulfonyl group, which are employable for the preparation of polymers comprising repeating unit represented by the formula above.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the stabilizer polymer composition of vinylsulfone or vinylsulfone precursor "H" of Formula I as taught by Wohlstadter et al. in view of Pierce et al. with an adhesive layer having the formula of Ogawa et al. in order to function as a stabilizer by improving adhesion between a support and a polyacrylamide gel medium.

23. Claims 27 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wohlstadter et al. (U.S. Patent No. 6,066,448, May 23, 2000) in view of Molteberg et al. (U.S. Patent No. 6,787,233, Published on Apr. 27, 2000).

Wohlstadter et al. teaches a microarray as discussed above. However, Wohlstadter et al. fails to teach a microarray, wherein the polymer particles comprise monodisperse polymer particles.

Molteberg et al. teaches a method of preparing monodisperse polymer particles comprising trimethylolpropane (column 2, line 62). The particles of Molteberg et al. may

be used for purposes in medical diagnostic assay and gene therapy (column 5, lines 63-64).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the microarray of Wohlstadter et al. with the polymer particles comprising trimethylolpropane of Molteberg et al. in order to use in applications such as medical diagnostic assay and gene therapy.

24. Claims 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wohlstadter et al. (U.S. Patent No. 6,066,448, May 23, 2000) in view of Snyder et al. (U.S. Patent No. 5,094,962, Mar. 10, 1992) as applied to claim 27 above, and further in view of Frechet et al. (U.S. Patent No. 5,306,561, Apr. 26, 1994).

Wohlstadter et al. in view of Snyder et al. teaches a microarray as discussed above. However, Wohlstadter in view of Snyder et al. fails to teach a microarray, wherein the polymer particles comprise at least one or more water-soluble ethylenically unsaturated monomers, which includes acrylic and methacrylic acids.

Frechet et al. teaches a method of producing polymer particles having a hydrophobic core and various surface functional groups, particularly hydrophilic and chiral surface functional groups (Abstract) resulting in polymer particles comprising water-soluble monomers such as acrylic and methacrylic acids (column 4, lines 54-68). The polymer particles (beads) are particularly useful in a variety of applications including enzyme immobilization (column 3, lines 44-50).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the microarray of Wohlstadter et al. in view of Snyder et al. with polymer particles comprising water-soluble ethylenically unsaturated monomers such as acrylic and methacrylic acids as taught by Frechet et al. in order to use in applications such as enzyme immobilization.

With respect to claim 32, Frechet et al. teaches one or more water-insoluble ethylenically unsaturated monomers, which comprise less than 20% of the total weight of the polymer particles (column 5, lines 27-31).

Double Patenting

25. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

26. Claims 1-4, 8-12, 12-15, 27-30, 34-37, 43, 51, and 52 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being

unpatentable over claims 27, 28, and 29-33 of copending Application No. 09/942,241 in view of Snyder et al. (U.S. Patent No. 5,094,962, Mar. 10, 1992).

Copending application teaches a microarray comprising a substrate coated with a compositing consisting of hydrophilic binder such as a gel containing a single layer of microspheres randomly distributed with a uniform density on the substrate, wherein the gel comprises a coating aid and gelling agent. However, copending application fails to teach that the layer is porous and that microspheres are polymer particles.

Snyder et al. teaches a method of preparing microporous article comprising a microporous substrate having stabilized specific binding reagent admixed with a hydrophilic binder material (Abstract, lines 1-6). The specific binding reagent comprises a water-insoluble particle, which is inert to all chemical and biological reactions other than reactions needed to attach receptor molecules and can be prepared from polymers (column 6, lines 5-24). The polymer particles used are spherical in shape having diameters ranging from 0.01-5 microns (column 6, lines 13-15). The microporous article of Snyder et al. is useful for the detection of a target ligand in an assay involving the specific binding reaction of the ligand with corresponding receptor molecules (Abstract, lines 14-17).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the microarray of copending application with the microporous substrate prepared from polymer particles, microspheres having diameters ranging from 0.01-5 microns, as taught by Snyder et al. in order to use as a coating

material for a substrate of a microarray to perform detection assay involving the specific binding reaction of the ligand with corresponding receptor molecules.

This is a provisional obviousness-type double patenting rejection.

27. Claims 1-4, 8-12, 12-15, 27-30, 34-37, 43, 51, and 52 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-16 of copending Application No. 10/062,326 in view of Snyder et al. (U.S. Patent No. 5,094,962, Mar. 10, 1992).

Copending application teaches a microarray comprising a support having at least one surface containing microspheres immobilized in a gelatin coating (hydrophilic binder), wherein a first portion of the microspheres is submerged in the gelatin coating and a second portion is exposed above the gelatin coating and is substantially free of gelatin. However, copending application fails to teach that the layer is porous and that microspheres are polymer particles.

Snyder et al. teaches a method of preparing microporous article comprising a microporous substrate having stabilized specific binding reagent admixed with a hydrophilic binder material (Abstract, lines 1-6). The specific binding reagent comprises a water-insoluble particle, which is inert to all chemical and biological reactions other than reactions needed to attach receptor molecules and can be prepared from polymers (column 6, lines 5-24). The polymer particles used are spherical in shape having diameters ranging from 0.01-5 microns (column 6, lines 13-15). The microporous article of Snyder et al. is useful for the detection of a target ligand in an assay involving the

specific binding reaction of the ligand with corresponding receptor molecules (Abstract, lines 14-17).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the microarray of copending application with the microporous substrate prepared from polymer particles, microspheres having diameters ranging from 0.01-5 microns, as taught by Snyder et al. in order to use as a coating material for a substrate of a microarray to perform detection assay involving the specific binding reaction of the ligand with corresponding receptor molecules.

This is a provisional obviousness-type double patenting rejection.

28. Claims 1-4, 8-12, 12-15, 27-30, 34-36, 43, 51, and 52 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of copending Application No. 10/625,424 in view of Snyder et al. (U.S. Patent No. 5,094,962, Mar. 10, 1992).

Copending application teaches a microarray comprising a support and a layer of microspheres bearing biological probes, wherein the microspheres comprise at least one material with a latent color that can be developed and used to identify the microsphere. However, copending application fails to teach that the layer is porous, which comprises hydrophilic binder and microspheres that are polymer particles.

Snyder et al. teaches a method of preparing microporous article comprising a microporous substrate having stabilized specific binding reagent admixed with a hydrophilic binder material (Abstract, lines 1-6). The specific binding reagent comprises

a water-insoluble particle, which is inert to all chemical and biological reactions other than reactions needed to attach receptor molecules and can be prepared from polymers (column 6, lines 5-24). The polymer particles used are spherical in shape having diameters ranging from 0.01-5 microns (column 6, lines 13-15). The microporous article of Snyder et al. is useful for the detection of a target ligand in an assay involving the specific binding reaction of the ligand with corresponding receptor molecules (Abstract, lines 14-17).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the microarray of copending application with the microporous substrate prepared from hydrophilic binder and polymer particles, microspheres having diameters ranging from 0.01-5 microns, as taught by Snyder et al. in order to use as a coating material for a substrate of a microarray to perform detection assay involving the specific binding reaction of the ligand with corresponding receptor molecules.

This is a provisional obviousness-type double patenting rejection.

29. Claims 1-4, 8-12, 12-15, 27-30, 34-37, 43, 51, and 52 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-16 of copending Application No. 10/625,637 in view of Snyder et al. (U.S. Patent No. 5,094,962, Mar. 10, 1992).

Copending application teaches a polymeric particle for use in a microarray comprising at least one functionally active group that can interact with a biological

probe, at least one photographic coupler and a high boiling solvent. However, copending application fails to teach that the layer is porous, which comprises hydrophilic binder and microspheres that are polymer particles.

Snyder et al. teaches a method of preparing microporous article comprising a microporous substrate having stabilized specific binding reagent admixed with a hydrophilic binder material (Abstract, lines 1-6). The specific binding reagent comprises a water-insoluble particle, which is inert to all chemical and biological reactions other than reactions needed to attach receptor molecules and can be prepared from polymers (column 6, lines 5-24). The polymer particles used are spherical in shape having diameters ranging from 0.01-5 microns (column 6, lines 13-15). The microporous article of Snyder et al. is useful for the detection of a target ligand in an assay involving the specific binding reaction of the ligand with corresponding receptor molecules (Abstract, lines 14-17).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the polymeric particle for use in a microarray as taught by of copending application with the microporous substrate prepared from hydrophilic binder and polymer particles, microspheres having diameters ranging from 0.01-5 microns, as taught by Snyder et al. in order to use as a coating material for a substrate of a microarray to perform detection assay involving the specific binding reaction of the ligand with corresponding receptor molecules.

This is a provisional obviousness-type double patenting rejection.

30. Claims 1-53 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-64 of copending Application No. 10/658,009 in view of Wohlstadter et al. (U.S. Patent No. 6,066,448, May 23, 2000).

Copending application teaches a polymer particle comprising a polymer bead stabilized by vinyl-functionalized polymer grafted to the surface of the bead. However, copending application fails to teach a polymer particle incorporated in a microarray with a hydrophilic binder.

Molteberg et al. teaches a method of preparing a microarray (column 11, lines 56-58) comprising a support having attached to a surface thereof at least one porous layer, wherein the porous layer comprises a hydrophilic binder (column 17, lines 17-19) and polymer particles (column 14, line 45-column 15, line 24 and column 15, lines 59-62). The polymer particles can be crosslinked (functionalized) using variety of coupling chemistries to integrate binding domains into the porous layer (column 15, lines 3-14). Molteberg et al. provide support surfaces for conducting a plurality of simultaneous assays for a plurality of analytes of interest in a single biological sample (column 3, lines 34-37).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to realize that the functionalized polymer particles of copending application can be used in a microarray as part of a porous layer comprising a hydrophilic binder and functionalized polymer particles as taught by Molteberg et al. in

order to conduct a plurality of simultaneous assays for a plurality of analytes of interest in a single biological sample

This is a provisional obviousness-type double patenting rejection.

31. Claims 1-53 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-65 of copending Application No. 10/682,271 in view of Snyder et al. (U.S. Patent No. 5,094,962, Mar. 10, 1992).

Copending application teaches a biological microarray comprising a support having disposed thereon at least one layer comprising filler and gelatin (hydrophilic binder), and at least one functional compound, wherein the functional compound comprises a first functional group capable of interacting with the gelatin and a second functional group capable of interacting with a biological capture agent, wherein the first functional group is the same as or different from the second functional group. However, copending application fails to teach that the layer is porous, which comprises hydrophilic binder and polymer particles as the filler.

Snyder et al. teaches a method of preparing microporous article comprising a microporous substrate having stabilized specific binding reagent admixed with a hydrophilic binder material (Abstract, lines 1-6). The specific binding reagent comprises a water-insoluble particle, which is inert to all chemical and biological reactions other than reactions needed to attach receptor molecules and can be prepared from polymers (column 6, lines 5-24). The polymer particles used are spherical in shape having

diameters ranging from 0.01-5 microns (column 6, lines 13-15). The microporous article of Snyder et al. is useful for the detection of a target ligand in an assay involving the specific binding reaction of the ligand with corresponding receptor molecules (Abstract, lines 14-17).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use polymer particles as a filler with a hydrophilic binder as taught by Snyder et al. with the microarray of copending in order to use polymer particles for as a specific binding reagent, which is inert to all chemical and biological reactions other than reactions needed to attach receptor molecules.

This is a provisional obviousness-type double patenting rejection.

32. Claims 1-4, 8-12, 12-15, 27-30, 34-37, 43, 51, and 52 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of copending Application No. 10/713,165 in view of Snyder et al. (U.S. Patent No. 5,094,962, Mar. 10, 1992).

Copending application teaches a coating composition for making a protein microarray, the composition comprising a gelling agent (hydrophilic binder) or a precursor to a gelling agent and microspheres. However, copending application fails to teach that the layer is porous, which comprises polymer particles as microspheres.

Snyder et al. teaches a method of preparing microporous article comprising a microporous substrate having stabilized specific binding reagent admixed with a hydrophilic binder material (Abstract, lines 1-6). The specific binding reagent comprises

a water-insoluble particle, which is inert to all chemical and biological reactions other than reactions needed to attach receptor molecules and can be prepared from polymers (column 6, lines 5-24). The polymer particles used are spherical in shape having diameters ranging from 0.01-5 microns (column 6, lines 13-15). The microporous article of Snyder et al. is useful for the detection of a target ligand in an assay involving the specific binding reaction of the ligand with corresponding receptor molecules (Abstract, lines 14-17).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the coating composition for making a protein microarray as taught by of copending application with the microporous substrate prepared from hydrophilic binder and polymer particles, microspheres having diameters ranging from 0.01-5 microns, as taught by Snyder et al. in order to use as a coating material for a substrate of a microarray to perform detection assay involving the specific binding reaction of the ligand with corresponding receptor molecules.

This is a provisional obviousness-type double patenting rejection.

33. Claims 1-4, 8-12, 12-15, 27-30, 34-37, 43, 51, and 52 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of copending Application No. 10/713,246 in view of Snyder et al. (U.S. Patent No. 5,094,962, Mar. 10, 1992).

Copending application teaches a coating composition for making a protein microarray, the composition comprising a gelling agent (hydrophilic binder) or a

precursor to a gelling agent and microspheres. However, copending application fails to teach that the layer is porous, which comprises polymer particles as microspheres.

Snyder et al. teaches a method of preparing microporous article comprising a microporous substrate having stabilized specific binding reagent admixed with a hydrophilic binder material (Abstract, lines 1-6). The specific binding reagent comprises a water-insoluble particle, which is inert to all chemical and biological reactions other than reactions needed to attach receptor molecules and can be prepared from polymers (column 6, lines 5-24). The polymer particles used are spherical in shape having diameters ranging from 0.01-5 microns (column 6, lines 13-15). The microporous article of Snyder et al. is useful for the detection of a target ligand in an assay involving the specific binding reaction of the ligand with corresponding receptor molecules (Abstract, lines 14-17).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the coating composition for making a protein microarray as taught by of copending application with the microporous substrate prepared from hydrophilic binder and polymer particles, microspheres having diameters ranging from 0.01-5 microns, as taught by Snyder et al. in order to use as a coating material for a substrate of a microarray to perform detection assay involving the specific binding reaction of the ligand with corresponding receptor molecules.

This is a provisional obviousness-type double patenting rejection.

34. Claims 1-4, 8-12, 12-15, 27-30, 34-37, 43, 51, and 52 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of copending Application No. 10/713,522 in view of Snyder et al. (U.S. Patent No. 5,094,962, Mar. 10, 1992).

Copending application teaches a coating composition for making a protein microarray, the composition comprising a gelling agent (hydrophilic binder) or a precursor to a gelling agent and microspheres. However, copending application fails to teach that the layer is porous, which comprises polymer particles as microspheres.

Snyder et al. teaches a method of preparing microporous article comprising a microporous substrate having stabilized specific binding reagent admixed with a hydrophilic binder material (Abstract, lines 1-6). The specific binding reagent comprises a water-insoluble particle, which is inert to all chemical and biological reactions other than reactions needed to attach receptor molecules and can be prepared from polymers (column 6, lines 5-24). The polymer particles used are spherical in shape having diameters ranging from 0.01-5 microns (column 6, lines 13-15). The microporous article of Snyder et al. is useful for the detection of a target ligand in an assay involving the specific binding reaction of the ligand with corresponding receptor molecules (Abstract, lines 14-17).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the coating composition for making a protein microarray as taught by of copending application with the microporous substrate prepared from hydrophilic binder and polymer particles, microspheres having diameters

ranging from 0.01-5 microns, as taught by Snyder et al. in order to use as a coating material for a substrate of a microarray to perform detection assay involving the specific binding reaction of the ligand with corresponding receptor molecules.

This is a provisional obviousness-type double patenting rejection.

Conclusion

35. No claims allowed.

36. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Unsu Jung whose telephone number is 571-272-8506. The examiner can normally be reached on M-F: 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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08/19/05